Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13335

7 - PROCEDURES

[redacted]

RADIOLOGY REPORT

NAME	NUMBER	SEX	AGE	ADMIT	DISC.	XRAY#	F/C	TYPE
[redacted]	[redacted]	M	38	12/30/98		[redacted]		

DATE OF BIRTH: [redacted] M/R# [redacted] PH#: [redacted]
LOCATION: TRANSCRIBED: 12/31/98 8:03
<= XRAY ORDER => COMPLETE: 12/30/98 18:43 [redacted]
Reason for Procedure: ACUTE ONSET OF AFIB
PORT CHEST [redacted] COMPLETE: 12/30/98 18:44 [redacted]
PHYSICIAN: [redacted]

PORTABLE EAP CHEST ON 12/30/98 AT 1830 HOURS:

CLINICAL HISTORY: Atrial fibrillation.

Comparison is made with chest x-ray of 5 June 92. The heart is enlarged with left ventricular prominence to the cardiac silhouette. Mediastinal contours are normal and the lungs are clear.

IMPRESSION: CARDIOMEGALY. LEFT VENTRICULAR PROMINENCE TO THE CARDIAC SILHOUETTE. NO ACUTE PULMONARY PATHOLOGY.

[redacted]
M.D.

[redacted]

[redacted]

NAME	NUMBER	SEX	AGE	ADMIT	DISC.	XRAY#	F/C	TYPE
[redacted]	[redacted]	M	38	12/30/98	1/01/99	[redacted]		

DATE OF BIRTH: [redacted] M/R# [redacted] PH#: [redacted]
LOCATION:
<= ECHO/CARDIO ORDER =>
Reason for Procedure: A FIB
US 2D M MODE ECHO [redacted]
PHYSICIAN: [redacted]

TRANSCRIBED: 1/04/99 7:17
COMPLETE: 12/31/98 8:39
COMPLETE: 12/31/98 8:39 [redacted]

M-MODE DIMENSIONS:

RV internal diameter	2.2 cm
interventricular septal thickness	1.2 cm
LV posterior wall thickness	1.2 cm
LV diastolic diameter	5.2 cm
LV systolic diameter	4.5 cm
Aortic root size	3.7 cm
Left atrial size	3.9 cm

2-D ANALYSIS: Technically limited study. Fair LV function. Normal LV size, normal LA size, normal RA and RV size. No intracardiac thrombus or pericardial effusion noted.

VALVES: Normal leaflet mobility without evidence of stenosis. Normal aortic root size. Mild left ventricular hypertrophy.

DOPPLER: No evidence of stenosis or regurgitation across any valves by color flow doppler.

IMPRESSION: TECHNICALLY LIMITED STUDY.
FAIR LV FUNCTION.
NORMAL LV SIZE.
MILD LVH.
UNREMARKABLE VALVES BY COLOR FLOW DOPPLER.
NORMAL LA SIZE.
EJECTION FRACTION 50%.

[redacted] M.D.

[redacted]

Echocardiography Report

DATE: 12/31/98

Name: [redacted] Age/Sex: 38M Ht:: ____ Wt: ____ lbs. Room [redacted]

Tape [redacted] Ref. Physician: [redacted] Sonographer: [redacted]

Clinical Diagnosis: A fib

☑ M-Mode ☑ 2-D ☐ Doppler ☑ C.F.M.

DIGITAL ON-LINE 2-D MEASUREMENT

R.V. Diastole	2.2 c.m.	(<3.0)	**Mitral Valve:** EPSS - 1.8 cm; EF Slope - 9.0 cm/sec
I.V.S. Thickness	1.2 c.m.	(<1.1)	
L.V.P.W. Thickness	~~1.0~~ 1.2 c.m.	(<1.1)	**Aortic Valve:**
L.V. Diastole	~~5.6~~ 5.2 c.m.	(<5.2)	AVD - 2.0 cm
L.V. Systole	4.5 c.m.	(<3.9)	**Tricuspid Valve:**
Aortic Root	3.7 c.m.	(<3.8)	
Left Atrium	3.9 c.m.	(<4.0)	**Pulmonic Valve:**
Global Ejection Fraction	~~40~~ 50 %	(>55%)	

Interpretation and Findings:

[illegible]

[redacted]

[redacted] Interpreting Physician

000004

[redacted]

[redacted]

RADIOLOGY REPORT

NAME	NUMBER	SEX	AGE	ADMIT	DISC.	XRAY#	F/C	TYPE
[redacted]		M	38	12/30/98				

DATE OF BIRTH: [redacted] M/R# [redacted] PH#: [redacted]

LOCATION: TRANSCRIBED: 12/31/98 14:16

<= XRAY ORDER => COMPLETE: 12/31/98 13:28

Reason for Procedure: EVAL SOB

CHEST W LATERAL [redacted] COMPLETE: 12/31/98 13:28

PHYSICIAN: [redacted]

Best Quality FDA

PA AND LATERAL CHEST ON 12/31/98:

CLINICAL HISTORY: Shortness of breath.

Comparison is made with the exam obtained one day prior to this. The heart is mildly enlarged. Mediastinal contours are normal, and the lungs are clear.

IMPRESSION: MILD CARDIOMEGALY. NO ACUTE PULMONARY PATHOLOGY.

[redacted] M.D.

[redacted]

[redacted]

DR [redacted]

THALLIUM SCAN

DATE: 01/05/99
AGE: 38
ROOM:
MR#: [redacted]
FILM#:

The patient had an exercise stress test. 4.3 mCi of thallium were injected at peak exercise. Films were obtained in the planar images. There is a stress defect seen in the inferior segment. Normal wash out on the anterior views. In the LAO 45, stress defect is seen in the septal segment with a normal washout. LAO 70 reveals a normal stress distribution with normal washout. The patient's test is non-diagnostic because a defect is seen in conflicting stress views with normal washout. Cannot rule out ischemia in the apical and inferior aspect. Clinical correlation is suggested.

IMPRESSION:
This is a non-diagnostic study due to a defect seen in conflicting stress views with normal washout. Cannot rule out ischemia in the apical and inferior aspect. Clinical correlation is suggested.

[redacted] M.D.

[redacted]

dd: 01/05/99 9:09 P dt: 01/06/99

cc: [redacted] M.D.
[redacted] M.D.

11/12 [redacted]

No f/u

[redacted]

[redacted]

THALLIUM SCAN

PATIENT: [redacted]
MR#: [redacted]
PHYSICIAN: [redacted] M.D.
ROOM#: [redacted]

000006

[redacted] 00:II 66/CI/IO

NARRATIVE SUMMARY

The patient was hooked up at 3:49 PM and was recorded for 23 hours 50 minutes. Four hours thirty three minutes were manually scanned due to artifact. The average heart rate was 99 BPM, with the minimum rate, 52 BPM, occurring at 5:29 AM, and the maximum rate, 147 BPM, occurring at 7:04 PM.

Ventricular ectopic activity consisted of 65 single beats. Ventricular beats occurred at the rate of 3.3 VEs per hour.

The patient's rhythm included 4 hours 5 minutes 12 seconds of tachycardia, 49 seconds of bradycardia. The fastest single episode of tachycardia occurred at 7:04 PM, lasting 174 beats and averaging 147 BPM. The slowest single episode of bradycardia occurred at 5:29 AM, lasting 10 beats and averaging 52 BPM.

Supraventricular ectopic activity consisted of 28 beats, of which 24 were PACs, and the remaining 4 were in atrial couplets. Supraventricular beats occurred at the rate of 1.4 SVEs per hour. There were 4 late beats. The longest R-R interval was .91 seconds.

TECHNICIAN COMMENTS

NO DIARY INFORMATION RECORDED.

Signed: _____ Date: _____

PATIENT NAME [redacted] [redacted] HOOK UP DATE : 06/15/99

ECTOPIC NARRATIVE (Non-Edited)

The Patient was monitored for a period of 23 hours and 42 minutes. The TOTAL NUMBER of BEATS was 141136 with an AVG RATE of 100. The Maximum BPM was 132 with the Minimum BPM of 82. WIDE BEATS totaled 58 representing <1% of all beats. WIDE COUPLETS totaled 3. WIDE RUNS totaled 0. PAUSES totaled 0. NARROW RUNS totaled 0. ISOLATED EARLY NARROW BEATS totaled 14 representing <1% of all beats. Total Minute(s) NOT ANALYZED: 0 representing 0 % of the study.

ISCHEMIC NARRATIVE

CH1-ST levels averaged +0.5 mm with the MAX of +1.3 mm and the MIN of -0.6 mm. Total Minutes in excess of 1 mm from the AVG was 1 representing < 1 % of the time monitored. The LONGEST duration in excess of 1 mm from AVG was 1 minutes with the onset at 06:21.

CH2-ST levels averaged +0.6 mm with the MAX of +1.6 mm and the MIN of -0.4 mm. Total Minutes in excess of 1 mm from the AVG was 0 representing 0 % of the time monitored. The LONGEST duration in excess of 1 mm from AVG was 0 minutes with the onset at -----.

CH3-ST levels averaged -0.5 mm with the MAX of +0.9 mm and the MIN of -2.1 mm. Total Minutes in excess of 1 mm from the AVG was 28 representing 2 % of the time monitored. The LONGEST duration in excess of 1 mm from AVG was 3 minutes with the onset at 13:49.

COMMENTARY / IMPRESSIONS

RATE: 82-122
AVERAGE RATE: 100
RHYTHM: SINUS RHYTHM/ SINUS TACH
PAUSES: NONE IDENTIFIED
ATRIAL ECTOPY: NONE IDENTIFIED
VENTRICULAR ECTOPY: VERY RARE PVC'S
ST CHANGES: BASELINE ST CHANGES
SYMPTOM CORRELATION: DIARY NOT RECORDED
CONCLUSION: SINUS RHYTHM/SINUS TACH RATE 82-122

[redacted] 000008

[redacted] M.D.

[redacted]

[redacted]

---PATIENT NAME---	SEX	AGE	BIRTH-DT	ADMIT	M/R#	PHYSICIAN
[redacted]	M	38	[redacted]	2/03/99	[redacted]	[redacted] ROOM: [redacted]

---PROCEDURE--- SGOT ORDER # [redacted]

--ORDERED--	--COLLECTED--	--REC'D--	--RESULTED--	--VERIFIED---
2/03/99 1339	2/03/99 1653	2/03/99 1653	2/03/99 1722	2/03/99 1722

[redacted] [redacted] [redacted] [redacted] [redacted]

[GO] SGOT ____17___ IU/L (L=15 H=47)]

000009

[redacted]

---PATIENT NAME----	SEX	AGE	BIRTH-DT	ADMIT	M/R#	PHYSICIAN
[redacted]	M	38	[redacted]	2/03/99	[redacted]	ROOM: [redacted]

---PROCEDURE---- CPK ORDER # [redacted]

--ORDERED--	--COLLECTED--	--REC'D--	--RESULTED--	--VERIFIED----
2/03/99 1338	2/03/99 1653	2/03/99 1653	2/03/99 1722	2/03/99 1722

[redacted]

[CK] CPK ____77___ IU/L (L=55 H=171)]

[redacted]

---PATIENT NAME---	SEX	AGE	BIRTH-DT	ADMIT	M/R#	PHYSICIAN
[redacted]	M	38	[redacted]	2/03/99	[redacted]	[redacted] ROOM: [redacted]

ORDER #[redacted]

---PROCEDURE---	--ORDERED--	--COLLECTED--	--REC'D--	--RESULTED--	--VERIFIED---
CKMB	2/03/99 1339	2/03/99 1653	2/03/99 1653	2/03/99 1910	2/03/99 1910

[redacted]

[MB] CKMB _____1.0_ U/L (L=0.10 H=5)]

[redacted]

---PATIENT NAME---	SEX	AGE	BIRTH-DT	ADMIT	M/R#	PHYSICIAN
[redacted]	M	38	[redacted]	2/03/99	[redacted]	[redacted] ROOM: [redacted]

---PROCEDURE---- TROPONIN-I ORDER # [redacted]

--ORDERED--	--COLLECTED--	--REC'D--	--RESULTED--	--VERIFIED---
2/03/99 1339	2/03/99 1653	2/03/99 1653	2/03/99 1910	2/03/99 1910

[redacted]

[TN] TROPONIN-I _____0.0_ NG/ML (L=0 H=2)]

000012

[redacted]

---PATIENT NAME---	SEX	AGE	BIRTH-DT	ADMIT	M/R#	PHYSICIAN
[redacted]	M	38	[redacted]	2/03/99	[redacted]	[redacted] ROOM: [redacted]

---PROCEDURE--- LDH ORDER # [redacted]

--ORDERED--	--COLLECTED--	--REC'D--	--RESULTED--	--VERIFIED---
2/03/99 1339	2/03/99 1653	2/03/99 1653	2/03/99 1722	2/03/99 1722

[redacted] [redacted] [redacted] [redacted] [redacted]

[LD] LDH ___443___ IU/L (L=313 H=618)]

000013

[redacted]

---PATIENT NAME---	SEX	AGE	BIRTH-DT	ADMIT	M/R#	PHYSICIAN
[redacted]	M	38	[redacted]	2/03/99	[redacted]	[redacted]

ROOM: [redacted]

ORDER # [redacted]

---PROCEDURE--- CPK

--ORDERED--	--COLLECTED--	--REC'D--	--RESULTED--	--VERIFIED---
2/04/99 0143	2/04/99 1815	2/04/99 1855	2/04/99 1926	2/04/99 1926
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[CK] CPK ____58____ IU/L (L=55 H=171)]

000014

[redacted]

RADIOLOGY REPORT

.....NAME.....	NUMBER	SEX	AGE	ADMIT	DISC.	XRAY#	F/C	TYPE
[redacted]	[redacted]	M	38	2/03/99		[redacted]		

DATE OF BIRTH: [redacted] M/R# [redacted] PH#: [redacted] RM [redacted]
LOCATION: TRANSCRIBED: 2/03/99 14:56
<= XRAY ORDER => COMPLETE: 02/03/99 11:37
Reason for Procedure: CHEST PAIN
PORT CHEST [redacted] COMPLETE: 02/03/99 11:37
PHYSICIAN: [redacted]

PORTABLE AP CHEST ON 02/03/99 AT 1140 HOURS:

Clinical information includes history of chest pain.

Comparison is made with previous chest x-ray dated 12/31/98.

The heart is mildly enlarged. The lungs are mildly underinflated. There is prominence of the upper lobe vasculature. There is haziness over the lower lung fields due to overlying chest soft tissues. No bony abnormality of the chest is recognized.

IMPRESSION: MILD CARDIAC ENLARGEMENT AND PROMINENCE OF UPPER LOBE VASCULATURE. I CANNOT EXCLUDE MILD PULMONARY VASCULAR CONGESTION. I SEE NO FOCAL PNEUMONIA OR INTERSTITIAL EDEMA.

[redacted]

[redacted]

RADIOLOGY REPORT

NAME	NUMBER	SEX	AGE	ADMIT	DISC.	XRAY#	F/C	TYPE
[redacted]	[redacted]	M	38	2/03/99		[redacted]		

DATE OF BIRTH: [redacted] M/R# [redacted] PH#: [redacted]

LOCATION: TRANSCRIBED: 2/04/99 9:13

<= NUC MED ORDER => COMPLETE: 02/03/99 22:26

Reason for Procedure: R/O PE

NM LUNG PERF ONLY [redacted] COMPLETE: 02/03/99 22:28

NM LUNG VENT BREATH/W.OUT COMPLETE: 02/03/99 22:28

PHYSICIAN: [redacted]

VENTILATION PERFUSION LUNG SCAN ON 02/03/99:

CLINICAL HISTORY: Shortness of breath.

The patient inhaled 21mCi Z9 133 gas. Initial breath, equilibrium and washout phases of the ventilation scan show no ventilation defects.

The patient was injected intravenously with 5.5mCi technetium 99m MAA. Multiple view were obtained for evaluation of pulmonary perfusion. No perfusion defects or other abnormalities are evident.

IMPRESSION: NO FINDINGS TO SUGGEST PULMONARY EMBOLUS.

NOTE SHOULD BE MADE THAT THIS EXAM WAS READ ON AN EMERGENCY BASIS BY DR. [redacted]

[redacted]

[redacted] M.D.

[redacted]

RADIOLOGY REPORT

---------NAME---------	NUMBER	SEX	AGE	ADMIT	DISC.	XRAY#	F/C	TYPE
[redacted]		M	38	2/03/99				

DATE OF BIRTH: [redacted] M/R# [redacted] PH#: [redacted] RM

LOCATION: TRANSCRIBED: 2/04/99 11:29

<= XRAY ORDER => COMPLETE: 02/04/99 1:48

Reason for Procedure: C/P

CHEST EPA/AP (1V) [redacted] COMPLETE: 02/04/99 10:42

PHYSICIAN: [redacted]

PA CHEST ON 02/04/99:

CLINICAL HISTORY: Chest pain.

Comparison is made with chest x-ray of 03 February 99. The heart is mildly enlarged. The mediastinal contours are normal. The lungs are clear.

IMPRESSION: MILD CARDIOMEGALY. NO ACUTE PULMONARY PATHOLOGY.

[redacted]

COPY

[redacted]

NAME [redacted] NUMBER [redacted] SEX M AGE 38 ADMIT 2/03/99 DISC. XRAY# [redacted] F/C [redacted] TYPE [redacted]

DATE OF BIRTH: [redacted] M/R# [redacted] PH#: [redacted] RM [redacted]

LOCATION: [redacted] TRANSCRIBED: 2/04/99 14:24

US CAROTID SCAN COMPLETE: 02/04/99 11:31

<= ECHO/CARDIO ORDER => COMPLETE: 02/04/99 11:30

Reason for Procedure: C/P

PHYSICIAN: [redacted]

RIGHT: There is minimal intimal thickening present. There is no significant plaque seen. There is no hemodynamically significant stenoses present. The right vertebral artery is patent with forward flow.

LEFT: There is minimal intimal thickening present. There is no significant plaque noted. There is no hemodynamically significant stenoses present. The left vertebral artery is patent with forward flow.

SUMMARY: THIS PATIENT HAS NO HEMODYNAMICALLY SIGNIFICANT STENOSES NOR IS THERE SIGNIFICANT PLAQUE IN EITHER CAROTID SYSTEM. THE VERTEBRAL SYSTEM IS PATENT WITH FORWARD FLOW. I CONSIDER THIS STUDY NORMAL FOR AGE. THIS REPORT WAS TELEPHONED TO THE NURSE CARING FOR THE PATIENT. I ASKED HER TO GIVE IT TO DR. [redacted]

[redacted]

D & T 2-4-99 [redacted] MD

COPY

[redacted]

NAME	NUMBER	SEX	AGE	ADMIT	DISC.	XRAY#	F/C	TYPE
[redacted]	[redacted]	M	38	2/03/99		[redacted]		

DATE OF BIRTH: [redacted] M/R# [redacted] PH#: [redacted] RM [redacted]
LOCATION: TRANSCRIBED: 2/04/99 14:22
<= ECHO/CARDIO ORDER => COMPLETE: 02/04/99 11:31
Reason for Procedure: R/O DVT
US VENOUS SCAN DUPLEX BIL [redacted] COMPLETE: 02/04/99 11:31
PHYSICIAN: [redacted]

RIGHT: The femoral-saphenous-popliteal system is identified. The vein walls are thin and collapse freely. Phasic flow, augmentation and color flow are present. The peroneal and distal popliteal system is identified. The thin vein walls collapse freely. Phasic flow, augmentation and color flow are present. The anterior tibial, posterior tibial and saphenous veins all demonstrate patency. Where anatomically possible, we are able to collapse these veins.

LEFT: The femoral-saphenous-popliteal system is identified. The vein walls are thin and collapse freely. Phasic flow, augmentation and color flow are present. The peroneal and distal popliteal system is identified. The thin vein walls collapse freely. Phasic flow, augmentation and color flow are present. The anterior tibial, posterior tibial and saphenous veins all demonstrate patency. Where anatomically possible, we are able to collapse these veins.

SUMMARY: THIS PATIENT HAS NO FINDINGS OF DEEP VENOUS THROMBOSIS. I TELEPHONED MY IMPRESSION TO THE NURSE CARING FOR THE PATIENT AND ASKED HER TO TELL DR. [redacted]

[redacted]
D & T: 2-4-99

[redacted] MD

000019

[redacted]

NAME	NUMBER	SEX	AGE	ADMIT	DISC.	MED.RECORD#	TYPE	ROOM#
[redacted]	[redacted]	M	38	2/03/99	2/05/99	[redacted]	[redacted]	

DATE OF BIRTH: [redacted] PHYSICIAN

PHYSICIAN: [redacted] MD [redacted]

Patient monitored 24 hours, 10 minutes. Sinus rhythm. Mean heart rate 78, minimum heart rate 49, maximum heart rate 122.

ATRIAL ACTIVITY: Rare PAC's. No nonsustained runs of supraventricular tachycardia noted.

VENTRICULAR ACTIVITY: Rare PVC's. No nonsustained runs of ventricular tachycardia noted.

ST SEGMENT SHIFTS: None.

PAUSES: None.

DIARY: No EKG correlation of symptoms of rushing feeling _____ chest pain.

IMPRESSION: SINUS RHYTHM RATE BETWEEN 49-122.
RARE PAC'S.
RARE PVC'S.
NO EKG CORRELATION OF ARRHYTHMIA.

[redacted], M.D.

[redacted]

D 02-05-99
T 02-09-99

[redacted]

Noted & placed on Flow Sheet [redacted]

[redacted]

PATIENT DEMOGRAPHIC DATA

Name: [redacted]
Age: 38
Source: [redacted]
Test Date: 02-05-99
Scanned By: [redacted]
Hook up tech: [redacted]
Medication: Medication status was not available.

ID Number: [redacted]
Sex: M
Doctor: [redacted]
Analysis Date: 02-08-99
Reading Physician: [redacted]
User Field 3:

Reason for test: CHEST PAIN

ANALYSIS SUMMARY

Heart Rate Data

Total Beats: 115784
Min HR: 52 BPM at 5:29am
Avg HR: 99 BPM
Max HR: 147 BPM at 7:04pm

Heart Rate Variability
(For Research Use Only)

ASDNN 5 : 29.9 msec
SDANN 5 : 76.2 msec
SDNN : 83.3 msec

ST Segment Analysis

	CH1	CH2	CH3
Min ST Level:	-	-	-
Avg ST Level:	-	-	-
Max ST Level:	-	-	-
ST Episodes :	-	-	-

Ventricular Ectopy

Total VE Beats.: 65
Vent Runs.....: -
Beats.....: -
Longest.....: -
Fastest.....: -
Triplets.....: -
Couplets.....: -
Single VEs.....: 65
R-on-T.....: -
Late VEs.....: -
Bi/Trigeminy.: -/-
Max VEs/Hour...: 16.7 ending 12:49pm

Supraventricular Ectopy

Total SVE Beats: 28
Atrial Runs....: -
Beats.....: -
Longest.....: -
Fastest.....: -
Atrial Pairs...: 2 events
Drop/Late.....: -/4
Longest.....: .91 sec at 1:36am
Single PAC's...: 24
Bi/Trigeminy.: -/-
Max SVEs/Hour..: 19.0 ending 5:49am

INTERPRETATION

Signed: [redacted] Date: 2/8/99

000021